

## PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>110108101/BLN</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/SE2004/001697</b>	International filing date (day/month/year) <b>19.11.2004</b>	Priority date (day/month/year) <b>20.11.2003</b>
International Patent Classification (IPC) or national classification and IPC See Supplemental Box		
<p>Applicant <b>Biosensor Applications Sweden AB (Publ) et al</b></p> <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>1</u> sheets, as follows:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input checked="" type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input checked="" type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>		

Date of submission of the demand <b>20.09.2005</b>	Date of completion of this report <b>05.12.2005</b>
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer <b>Malin Söderman/EK</b> Telephone No. +46 8 782 25 00

## Box No. I Basis of the report

1. With regard to the language, this report is based on:

the international application in the language in which it was filed  
 a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:  
 international search (Rules 12.3(a) and 23.1(b))  
 publication of the international application (Rule 12.4(a))  
 international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished  
 the description:

pages 1 - 9 as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages 10, 11 as originally filed/furnished  
 pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages 1, 3 as originally filed/furnished  
 pages\* 2 received by this Authority on 20.09.2005  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

PCT/SE2004/001697

**Box No. II Priority**

1.  This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
  - copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
  - translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2.  This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

The priority is considered valid. Document WO04001392 A1 is therefore of no relevance.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001697

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	<u>1-16</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-16</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-16</u>	YES
	Claims	_____	NO

## 2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: US5306644 A1

D2: WO0043774 A2

D3: US6294391 B1

The invention relates to a mixture of isolated or synthetic affinity molecules in a liquid carrier. The mixture comprises at least two different affinity molecules, each with affinity for a predetermined analyte, for use in a single or multi flow cell piezoelectric crystal micro balance apparatus. Each isolated or synthetic affinity molecule forms together with the predetermined analyte an interaction pair selected from the group consisting of anion-cation, anti body-antigen, receptor-ligand, enzyme-substrate, oligonucleotide-oligonucleotide with complementary sequence, oligonucleotide-protein, oligonucleotide-cell, and peptide nucleic acid (PNA) oligomer - polynucleotide, wherein the polynucleotide may be selected from the group consisting of RNA, DNA and PNA polymers complementary to the PNA oligomer.

Use of the mixture for introduction into the liquid flow of a single or multi flow cell piezoelectric crystal micro balance apparatus is also described, as well as a kit containing the mixture.

D1 describes a system for measurement of one or several analytes in a system, see abstract. The measurement system comprises piezoelectric surface wave sample devices. According to D1, the detection of analytes can be based on

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/SE2004/001697

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO04001392 A1, PX	31.12.2003	18.06.2003	19.06.2002

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box V**

competition, see column 9, lines 4-16. Multiple analytes could be analysed from a single sample by arranging the measuring devices in series, see column 13, lines 4-14, fig. 6. In column 17, lines 58-61, D1 states that the analytes are low molecular weight compounds, like amphetamine. The devices could be recycled by treatment with acetic acid, see column 17, lines 55-57 and refreshed or regenerated after each measurement, see column 10, lines 4-14.

D2 describes a method where an antigen is bound to a quartz crystal. An antibody solution is mixed with a sample that can contain the analyte. Different results are achieved depending on if the analyte is present or not.

D3 discloses the use of glycine to remove a binding partner or analyte analogue from a solid support, see D3, column 4, lines 36-54. D3 describes a method where a solid support comprises an analyte analogue and a binding partner immobilised on the surface by interaction with the analogue, see claims 1-8. The binding partner is displaced from the solid support in response to the presence of an analyte.

The cited documents represent the general state of the art.

The invention defined in claims 1-16 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed use of mixture of affinity molecules in a liquid carrier in a flow cell piezoelectric crystal micro balance apparatus for detecting analytes. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-16 is novel and is considered to involve an inventive step. The invention is industrially applicable.

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

PCT/SE2004/001697

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient,

Continuation of: **Cover sheet**

**G01N 33/543 (2006.01)**

**G01N 33/553 (2006.01)**

**H01L 41/00 (2006.01)**

20 -09- 2005

2/3

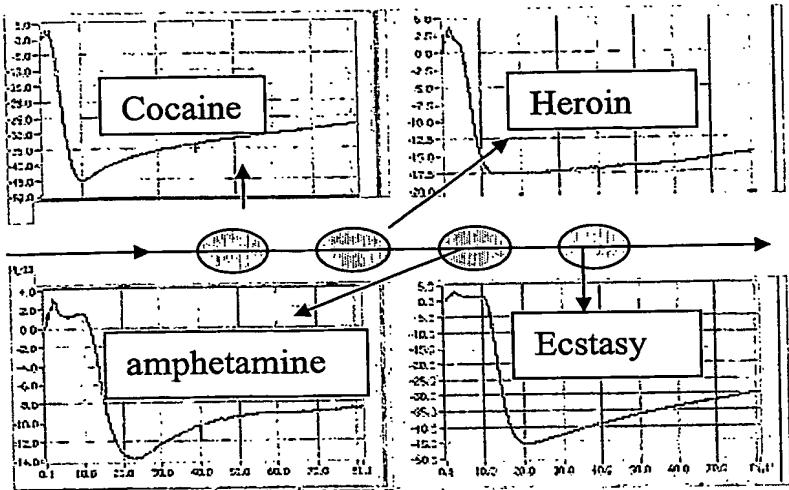


Fig. 3

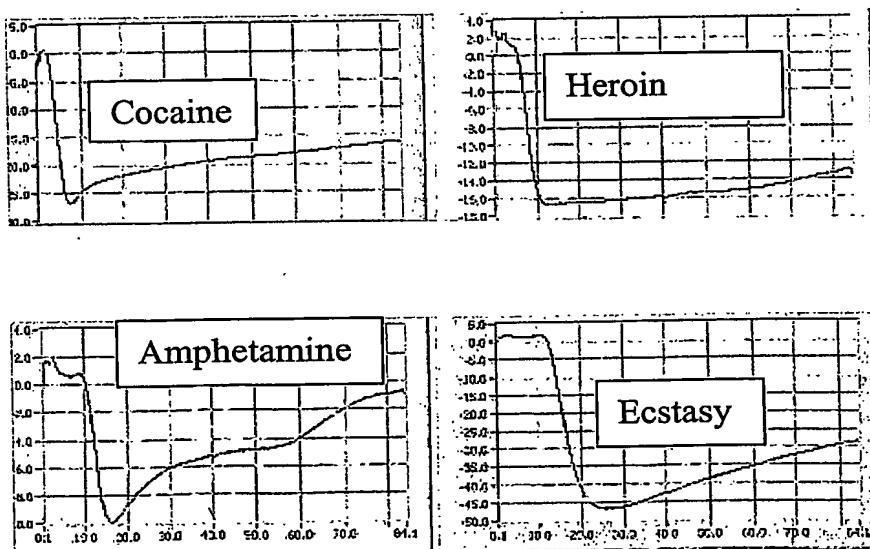


Fig. 4